PRODUCT DESCRIPTION

Fluorescent Immunoassay Analyzer

Biohit Healthcare (Hefei) Co., Ltd.

CONTENT

1. General description

1.1. Instrument introduction

Product name: Fluorescent Immunoassay Analyzer

Product model: BOH-180

Product dimensions: 160mm×108mm×72mm

Product weight: 0.7kg

Operation mode: continuously working

Service life:10 years

1.2. Software introduction

Software name: BOH-180 Fluorescent Immunoassay Analyzer

System requirement: Android 4.4 ~ Android 8

Hardware requirement: 1.2GHz or higher quad core processor, 1GB or more RAM, 4GB or more storage.

2. Structure composition

The product is composed of main unit and the power adapter. The main unit is composed of measurement module, power adapter, screen and outer case.

2.1. Instrument outer structure diagram

Instrument dimensions:160mm×108mm×72mm

Front structure diagram:

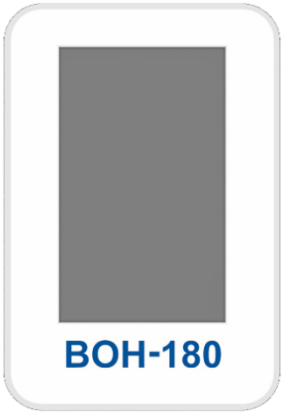

Figure 1. Fluorescent Immunoassay Analyzer front structure diagram

Left side structure diagram:

Figure 2. Fluorescent Immunoassay Analyzer left side structure diagram

Right side structure diagram:

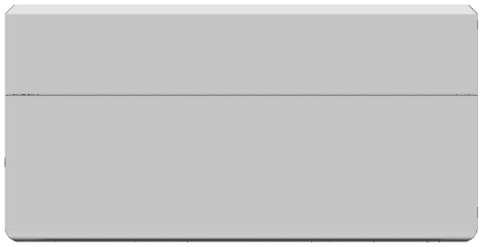

Figure 3. Fluorescent Immunoassay Analyzer right side structure diagram

Back structure diagram:

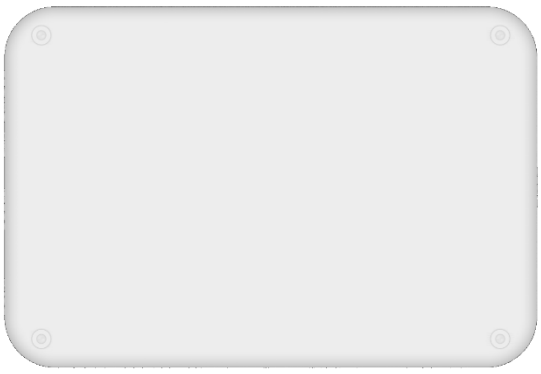

Figure 4. Fluorescent Immunoassay Analyzer back structure diagram

Power adapter:

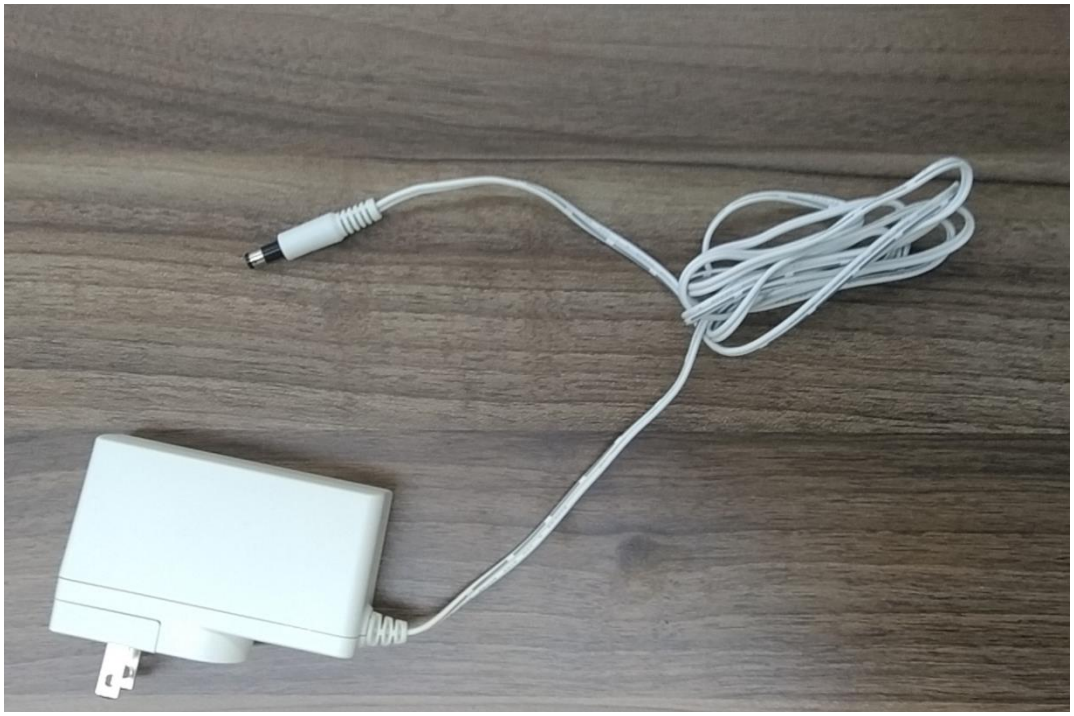

Figure 5. Power adapter

2.2. Instrument components(including accessories)

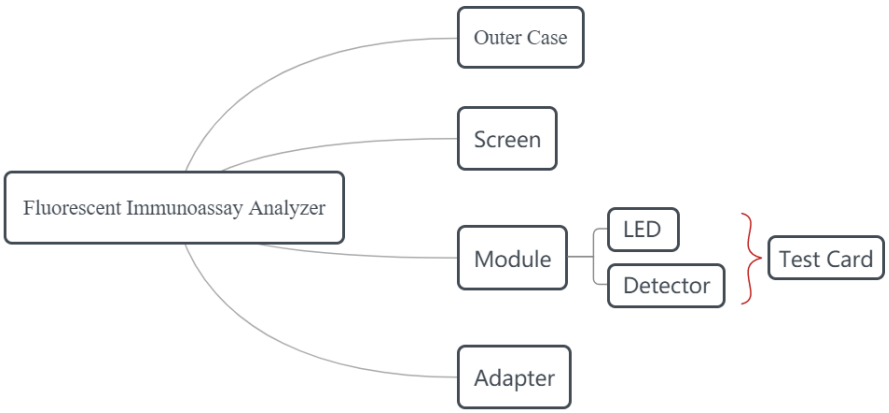

Figure 6. Fluorescent Immunoassay Analyzer components

3. Intended use

This product is intended for the fluorescence immunoassay and analysis of dedicated fluorescence testing card.

4. Expected applicable environment

Ambient temperature:5℃~40℃

Relative humidity:80%

Atmospheric Pressure:86.0kPa~106.0kPa

Power Input:100~240Vac 50Hz

Host Input :⎓12V

Input power:8W

5. Product working principle

Fluorescent Immunoassay Analyzer is a fluorescence detection system based on the principle of photoelectric detection. Fluorescence material can generate stable fluorescence signals under the excitation light. By detecting the amplitude of the fluorescence signal, quantitative fluorescence detection can be carried out as follows:

As shown in Fig. 7, the sample to be tested is added to the sampling well on the testing card, and the analyte in the sample forms a complex with the antibody labeled with the fluorescent microspheres on the binding pad under the action of chromatography. The complex continues to be chromatographed to the testing area(T line) on the nitro cellulose membrane and is captured by the antibody in the testing area. The more fluorescent particles in the testing area, the stronger the fluorescence signal in the testing area, the ratio of the fluorescence signal between the testing areaand the control zone (C line) is proportional to the amount of the analyte present in the sample.

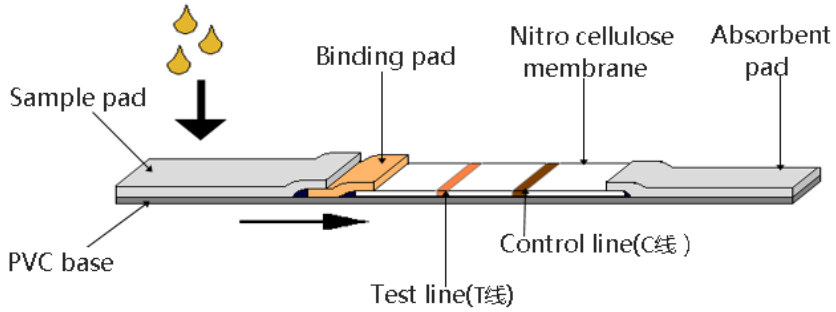

Figure 7. Testing card internal structure diagram

According to the above relationship, photoelectric detection and motor drive circuit controlled by the single-chip control unit's signal drive the linear motor to achieve point-by-point scanning. During the scanning process, the LED lights are turned on to generate the excitation light, and the excitation light passes through the slit and the filter and then illuminates on the sample. The material in the sample is excited to generate the fluorescence signal. After the fluorescent signal passes through the slit and the filter, the optical signal is converted into the electric signal by the high sensitivity photodiode, and then the digital signal corresponding to the fluorescence intensity value is obtained after amplification, filtering and analog-to-digital conversion. During the scanning process, the single-chip control unit synchronize the linear motor and the analog-to-digital conversion until the fluorescence intensity measurement of the entire testing card detection area is completed. The result of analog-to-digital conversion of each scanning point is sent to the host computer control software through the communication interface. Finally, the control software converts the scan result to the corresponding concentration through the algorithm and displays it to the user. As shown in Figure 8,9:

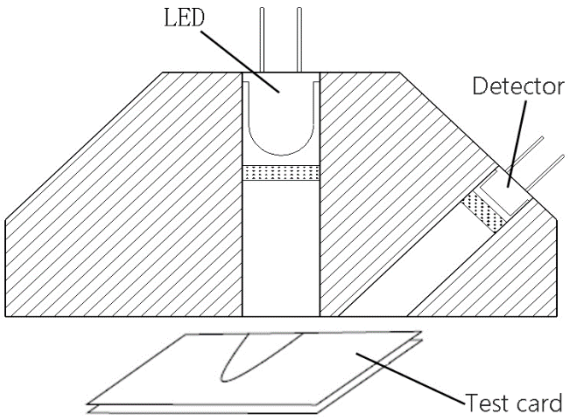

Figure 8. Light path structure diagram

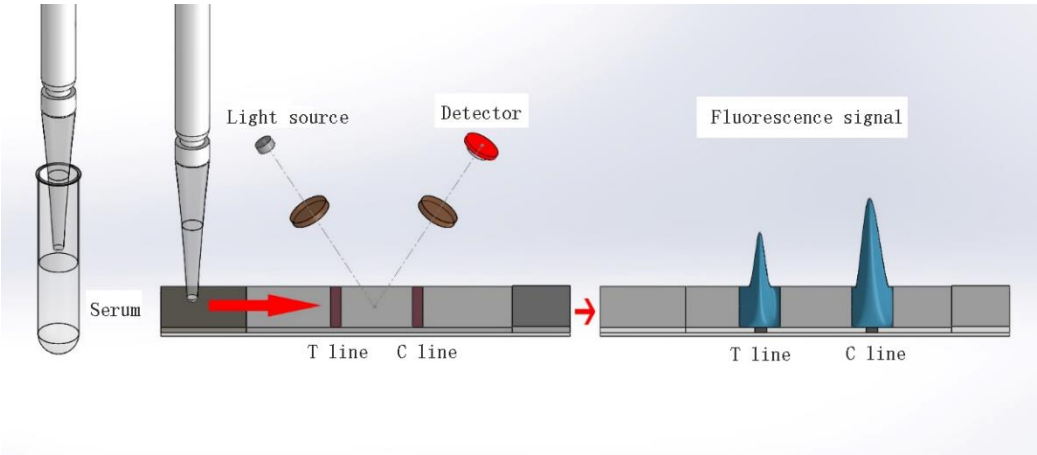

Figure 9. Product operation principle

6. Product classification

According to the list in Annex II of 98/79/EEC, this product is classified in “other” category.

7. Conformity assessment route options

In accordance with Article 9 of the Directive 98/79 / EEC, we shall implement the conformity assessment procedure specified in Appendix III.